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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/098,505 | 03/18/2002 | Annapurna Jetty | 033432-015 | 4407 |
| 7590 | 12/04/2003 | | EXAMINER | |
| Norman H. Stepno, Esquire BURNS, DOANE, SWECKER & MATHIS, L.L.P. P.O. Box 1404 Alexandria, VA 22313-1404 | | | LILLING, HERBERT J | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1651 | |

DATE MAILED: 12/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/098,505 | JETTY ET AL. |
| | Examiner | Art Unit |
| | HERBERT J LILLING | 1651 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 October 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 9 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 9-10 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - a) The translation of the foreign language provisional application has been received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

1. Receipt is acknowledged of the response filed October 14, 2003.

2. Claims 9-10 are pending in this application.

Claims 1-8 have been cancelled.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9 and 10 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention with respect to the microorganism per se, see the following paragraphs: the deposit lacks the following conditions: under

[37 CFR 1.808 Furnishing of samples]

(a) A deposit must be made under conditions that assure that:

(1) Access to the deposit will be available during pendency of the patent application making reference to the deposit to one determined by the Commissioner to be entitled thereto under 1.14 and 35 U.S.C. 122, and

(2) Subject to paragraph (b) of this section, all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent.

(b) The depositor may contract with the depository to require that samples of a deposited biological material shall be furnished only if a request for a sample, during the term of the patent:

- (1) Is in writing or other tangible form and dated;
 - (2) Contains the name and address of the requesting party and the accession number of the deposit; and
 - (3) Is communicated in writing by the depository to the depositor along with the date on which the sample was furnished and the name and address of the party to whom the sample was furnished.
- (c) Upon request made to the Office, the Office will certify whether a deposit has been stated to have

been made under conditions which make it available to the public as of the issue date of the patent grant provided the request contains:

- (1) The name and address of the depository;
- (2) The accession number given to the deposit;
- (3) The patent number and issue date of the patent referring to the deposit; and
- (4) The name and address of the requesting party.

and

[**2410.01 Conditions of Deposit**]

37 CFR 1.808 requires that the deposit of biological material be made under two (2) conditions:

- (1) access to the deposit will be available during pendency of the patent application making reference to the deposit to one determined by the Commissioner to be entitled thereto under 37 CFR 1.14 and 35 U.S.C. 122, and
- (2) with one exception, that all restrictions imposed by the depositor on the availability to the public of the deposited biological material be irrevocably removed upon the granting of the patent. The one exception that is permitted is specified in 37 CFR 1.808(b) which permits the depositor to contract with the depository to require that samples of a deposited biological material shall be furnished only if a request for a sample, during the term of the patent, meets any one or all of the three conditions specified in this paragraph. These conditions are:

- (1) the request is in writing or other tangible form and dated; and/or
- (2) the request contains the name and address of the requesting party and the accession number of the deposit; and/or
- (3) the request is communicated in writing by the depository to the depositor along with the date on which the sample was furnished and the name and address of the party to whom the sample was furnished.

It should be noted that this exception to the general rule that all restrictions will be removed must be strictly followed and that no variations of this explicit exception will be accepted as meeting the

conditions of this section. Although this exception is consistent with the provisions in the Budapest Treaty and its implementing regulations (Rule 11.4), other conditions on accessibility are permitted under the Budapest Treaty as prescribed by national law. Consequently, the mere indication that a deposit has been made under conditions prescribed by the Budapest Treaty would satisfy all conditions of these regulations except the requirement that all restrictions on access be removed on grant of the patent. *Ex parte Hildebrand*, 15 USPQ2d 1662 (Bd Pat. App. & Int. 1990).

2410.02 Certification of Accessibility of Deposit

Since the mere description of a deposit or identity of a deposit in a patent specification is not necessarily an indication that a requirement for deposit was made or that a deposit which complies with these rules has been made, accessibility to a deposited material referenced in a patent may depend on the satisfaction of conditions not apparent on the face of the patent. For these reasons, and upon request made to the Patent and Trademark Office, the Office will certify whether a deposit has been stated to have been made under conditions which would make it available to the public as of the issue date of the patent grant provided the request is made to the Director of Patent Examining Group 1800, and contains the following information:

- (1) the name and address of the depository;
- (2) the accession number given to the deposit;
- (3) the patent number and issue date of the patent referring to the deposit; and
- (4) the name and address of the requesting party.

For those deposits made pursuant to the Budapest Treaty, the World Intellectual Property Organization provides a form (Form BP - 12) for requesting a certification of the availability of samples of deposited micro - organisms.

There are two outstanding problems which applicant is kindly requested to put clarify:

a) there is no indication with the current list of depositories that Imtec Depository is a fully recognized depository in India at Chandigarh, India. Applicant is requested to submit evidence that this Depository is fully recognized as a Depository;

and

b) applicant is required to submit a statement pertaining to the above requirement as to the availability of the deposit in accordance with U.S. Rules of Deposit—a statement by Attorney or Applicant that --- all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of the patent----would be sufficient to overcome the above rejection.

4. **No claim is allowed.**

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is (703) 308-2034 or SPE Michael Wityshyn whose telephone number is (703) 308-4743. Examiner can be reached Monday-Thursday from 5:30 A.M. to about 3:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

H.J.Lilling: HJL
(703) 308-2034
Art Unit 1651
November 24, 2003

Herbert J. Lilling
Herbert J. Lilling
Primary Examiner
Group 1600 Art Unit 1651